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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,359	10/21/2003	John C. Gerdes	XTR004CIP-DIV	3862
25235	7590	10/26/2005	EXAMINER	
HOGAN & HARTSON LLP ONE TABOR CENTER, SUITE 1500 1200 SEVENTEENTH ST DENVER, CO 80202			WHISENANT, ETHAN C	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/690,359	GERDES ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**NON-FINAL ACTION**

1. The applicant's Preliminary Amendment filed 11 FEB 04 has been entered. Following the entry of the Preliminary Amendment, Claim(s) 1-9 is/are pending.

**SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

**Non-Statutory Obviousness-type Double Patenting Rejection**

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **Claim(s) 1-2, 4 and 9** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-14 of U.S. Patent No. 6,291,166 in view of the Stratagene Catalog (1988).

Claims 1-14 of U.S. Patent No. 6,291,166 teach a method of manipulating nucleic acids comprising the kit components recited in Claims 1-2, 4 and 9. Claims 1-14 of U.S. Patent No. 6,291,166

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do not teach placing the reagents necessary to perform the method of Claims 1-14 into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition, the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-14 of U.S. Patent No. 6,291,166 with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method of Claims 1-14 of U.S. Patent No. 6,291,166 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

5. **Claim(s) 1-9** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-31 of U.S. Patent No. 6,872,527 in view of the Stratagene Catalog (1988).

Claims 1-31 of U.S. Patent No. 6,872,527 teach a method of manipulating nucleic acids comprising the kit components recited in Claims 1-8. Claims 1-14 of U.S. Patent No. 6,291,166 do not teach placing the reagents necessary to perform the method of Claims 1-14 into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. In addition, the Stratagene catalog teaches the advantages of assembling a kit, such as, saving resources and reducing waste. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-14 of U.S. Patent No. 6,291,166 with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method of Claims 1-14 of U.S. Patent No. 6,291,166 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.


#### CONCLUSION

6. **Claim(s) 1-9** is/are rejected and/or objected to for the reason(s) set forth above.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The Central Fax number for the USPTO is (571) 273-8300. Before faxing any papers, please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**ETHAN WHISENANT**  
**PRIMARY EXAMINER**

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